

**REMARKS**

Claim 1 has been amended. The support for the amendment to claim 1 is found on page 7, lines 26-29 of the present specification.

Claims 1 and 3-19 and 21-24 remain rejected under 35 USC § 102(b) as being anticipated by Kolter et al. (DE 197 09 663).

Kolter et al.'s disclosure is restricted to 0.5 to 20%. Applicant's formulated mixture is from 20 to 80%. Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Corp., v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Kolter et al. do not teach each and every element of amended claim 1.

Claims 1, 4-5, 8-12 and 15-19 and 21-22 and 24 are rejected under 35 USC § 102(b) as being anticipated by Ortega (US 4,837,032).

Ortega et al. do not disclose a solid oral dosage forms which contains **preformulated** mixtures. This is a positive limitation in applicants' present claim 1. Therefore, Ortega et al. do not anticipate the present invention.

Claims 1 and 3-19 and 21-24 are rejected under 35 USC § 103(a) as being unpatentable over Kolter et al. (DE 197 09 663).

It was not expected that varying amounts of PVP/PVAc would lead to tablets with delayed release and a much higher tablet hardness. Applicants also believe that "delayed release" is not a subject term. Applicants enclose a copy from a textbook

which clearly shows that delayed release is defined in USP XII and a copy from USP 23 defining immediate release and testing times of up to one hour as appropriate for immediate release. A release occurring over one hour would not be regarded as a delayed release by one of ordinary skill in the art.

Claims 1, 4-5, 8-12 and 15-19, 21-22 and 24 are rejected under 35 USC § 103(a) as being unpatentable over Ortega (4,837,032). The examiner believes Ortega teaches delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures with water-soluble polymers. The examiner also believes the amounts of ingredients are within the instant claimed ranges and manipulation of ingredients would have been obvious to one skilled in the art at the time of the invention with the motivation of adjusting the binding effects of the composition. The examiner stated that applicants' arguments in the last response are not persuasive because advantages such as hardness are not included as features in the claims.

Applicants disagree with the examiner because the unexpected advantages are due to the formulated mixture of polyvinylpyrrolidone and polyvinyl acetate which is a feature of claim 1 as b). Unexpected advantages typically are not included as limitations in claims.

Claims 1, 3-19 and 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of US 6,066,334.

The examiner stated that the obviousness double patenting rejection is

maintained on the basis that the instant claims do not differentiate delayed release from the release profile set forth in '334 which provides delayed release over an hour but no limitations regarding the content as being between 20 to 60% are in the claims.

With the present amendment, applicants add a limitation that the formulated mixture is between 20 to 80%. Therefore, applicants believe the double patenting rejection has been overcome.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn.

**A check in the amount of \$410.00 is attached to cover the required fee for a two month extension of time.**

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such account.

Respectfully submitted,

KEIL & WEINKAUF



Daniel S. Kim  
Reg. No. 51,877

KOLTER et al., Serial No. 09/811,546

1350 Connecticut Ave., N.W.  
Washington, D.C. 20036  
(202)659-0100

DSK/kas